

listed chemicals or controlled substances will subject themselves not only to State or Federal prosecution for any illicit activity, but shall also immediately become the subject of independent action regarding their continued employment. The employer will assess the seriousness of the employee's violation, the position of responsibility held by the employee, past record of employment, etc., in determining whether to suspend, transfer, terminate or take other action against the employee.

§ 1309.73 Employee responsibility to report diversion.

Reports of listed chemical diversion by fellow employees is not only a necessary part of an overall employee security program but also serves the public interest at large. It is, therefore, the position of DEA that an employee who has knowledge of diversion from his employer by a fellow employee has an obligation to report such information to a responsible security official of the employer. The employer shall treat such information as confidential and shall take all reasonable steps to protect the confidentiality of the information and the identity of the employee furnishing information. A failure to report information of chemical diversion will be considered in determining the feasibility of continuing to allow an employee to work in an area with access to chemicals. The employer shall inform all employees concerning this policy.

PART 1310—RECORDS AND REPORTS OF LISTED CHEMICALS AND CERTAIN MACHINES

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AUTHORITY: 21 U.S.C. 802, 830, 871(b).

SOURCE: 54 FR 31665, Aug. 1, 1989, unless otherwise noted.

§ 1310.01 Definitions.

Any term used in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter.

[62 FR 13968, Mar. 24, 1997]

§ 1310.02 Substances covered.

The following chemicals have been specifically designated by the Administrator of the Drug Enforcement Administration as the listed chemicals subject to the provisions of this part and parts 1309 and 1313 of this chapter. Each chemical has been assigned the DEA Chemical Code Number set forth opposite it.

(a) List I chemicals

- (1) Anthranilic acid, its esters, and its salts8530
- (2) Benzyl cyanide.....8735
- (3) Ephedrine, its salts, optical isomers, and salts of optical isomers8113
- (4) Ergonovine and its salts8675
- (5) Ergotamine and its salts.....8676
- (6) N-Acetylanthranilic acid, its esters, and its salts.....8522
- (7) Norpseudoephedrine, its salts, optical isomers, and salts of optical isomers8317
- (8) Phenylacetic acid, its esters, and its salts.....8791
- (9) Phenylpropanolamine, its salts, optical isomers, and salts of optical isomers1225
- (10) Piperidine and its salts2704
- (11) Pseudoephedrine, its salts, optical isomers, and salts of optical isomers.....8112
- (12) 3,4-Methylenedioxyphenyl-2-propanone8502
- (13) Methylamine and its salts.....8520
- (14) Ethylamine and its salts8678
- (15) Propionic anhydride.....8328
- (16) Isosafrole.....8704
- (17) Safrole.....8323
- (18) Piperonal.....8750

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- (19) N-Methylephedrine, its salts, optical isomers, and salts of optical isomers (N-Methylephedrine)8115
- (20) N-Methylpseudoephedrine, its salts, optical isomers, and salts of optical isomers8119
- (21) Hydriodic Acid6695
- (22) Benzaldehyde.....8256
- (23) Nitroethane6724

(b) List II chemicals:

- (1) Acetic anhydride.....8519
- (2) Acetone.....6532
- (3) Benzyl chloride.....8570
- (4) Ethyl ether6584
- (5) Potassium permanganate6579
- (6) 2-Butanone (or Methyl Ethyl Ketone or MEK)6714
- (7) Toluene.....6594
- (8) Hydrochloric acid6545
- (9) Sulfuric acid6552
- (10) Methyl Isobutyl Ketone (MIBK)6715

(c) The Administrator may add or delete a substance as a listed chemical by publishing a final rule in the FEDERAL REGISTER following a proposal which shall be published at least 30 days prior to the final rule.

(d) Any person may petition the Administrator to have any substance added or deleted from paragraphs (a) or (b) of this section.

(e) Any petition under this section shall contain the following information:

- (1) The name and address of the petitioner;
- (2) The name of the chemical to which the petition pertains;
- (3) The name and address of the manufacturer(s) of the chemical (if known);
- (4) A complete statement of the facts which the petitioner believes justifies the addition or deletion of the substance from paragraphs (a) or (b) of this section;
- (5) The date of the petition.

(f) The Administrator may require the petitioner to submit such documents or written statements of fact relevant to the petition as he deems necessary in making a determination.

(g) Within a reasonable period of time after the receipt of the petition, the Administrator shall notify the petitioner of his decision and the reason therefor. The Administrator need not accept a petition if any of the requirements prescribed in paragraph (e) of this section or requested pursuant to

paragraph (f) of this section are lacking or are not clearly set forth as to be readily understood. If the petitioner desires, he may amend and resubmit the petition to meet the requirements of paragraphs (e) and (f) of this section.

(h) If a petition is granted or the Administrator, upon his own motion, proposes to add or delete substances as listed chemicals as set forth in paragraph (c) of this section, he shall issue and publish in the FEDERAL REGISTER a proposal to add or delete a substance as a listed chemical. The Administrator shall permit any interested person to file written comments regarding the proposal within 30 days of the date of publication of his order in the FEDERAL REGISTER. The Administrator will consider any comments filed by interested persons and publish a final rule in accordance with his decision in the matter.

[54 FR 31665, Aug. 1, 1989, as amended at 56 FR 48733, Sept. 26, 1991; 57 FR 43615, Sept. 22, 1992; 60 FR 19510, Apr. 19, 1995; 60 FR 32460, June 22, 1995; 62 FR 5917, Feb. 10, 1997]

§ 1310.03 Persons required to keep records and file reports.

(a) Each regulated person who engages in a regulated transaction involving a listed chemical, a tableting machine, or an encapsulating machine shall keep a record of the transaction as specified by § 1310.04 and file reports as specified by § 1310.05. However, a non-regulated person who acquires listed chemicals for internal consumption or “end use” and becomes a regulated person by virtue of infrequent or rare distribution of a listed chemical from inventory, shall not be required to maintain receipt records of listed chemicals under this section.

(b) Each regulated person who manufactures a List I or List II chemical shall file reports regarding such manufacture as specified in Section 1310.05.

[54 FR 31665, Aug. 1, 1989, as amended at 56 FR 8277, Feb. 28, 1991; 61 FR 14023, Mar. 29, 1996]

§ 1310.04 Maintenance of records.

(a) Every record required to be kept subject to § 1310.03 for a List I chemical, a tableting machine, or an encapsulating machine shall be kept by the

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regulated person for 2 years after the date of the transaction.

(b) Every record required to be kept subject to Section 1310.03 for List II chemical shall be kept by the regulated person for two years after the date of the transaction.

(c) A record under this section shall be kept at the regulated person's place of business where the transaction occurred, except that records may be kept at a single, central location of the regulated person if the regulated person has notified the Administration of the intention to do so. Written notification must be submitted by registered or certified mail, return receipt requested, to the Special Agent in Charge of the DEA Divisional Office for the area in which the records are required to be kept.

(d) The records required to be kept under this section shall be readily re-

trievable and available for inspection and copying by authorized employees of the Administration under the provisions of 21 U.S.C. 880.

(e) The regulated person with more than one place of business where records are required to be kept shall devise a system to detect any party purchasing from several individual locations of the regulated person thereby seeking to avoid the application of the cumulative threshold or evading the requirements of the Act.

(f) For those listed chemicals for which thresholds have been established, the quantitative threshold or the cumulative amount for multiple transactions within a calendar month, to be utilized in determining whether a receipt, sale, importation or exportation is a regulated transaction is as follows:

(1) List I Chemicals:

Chemical	Threshold by base weight
(i) Anthranilic acid and its salts	30 kilograms.
(ii) Benzyl cyanide	1 kilogram.
(iii) Ergonovine and its salts	10 grams.
(iv) Ergotamine and its salts	20 grams.
(v) N-Acetylanthranilic acid and its salts	40 kilograms
(vi) Norpseudoephedrine, its salts, optical isomers, and salts of optical isomers	2.5 kilograms.
(vii) Phenylacetic acid and its salts	1 kilogram.
(viii) Phenylpropanolamine, its salts, optical isomers, and salts of optical isomers	2.5 kilograms.
(ix) Piperidine and its salts	500 grams.
(x) Pseudoephedrine, its salts, optical isomers, and salts of optical isomers	1 kilogram
(xi) 3, 4-Methylenedioxyphenyl-2-propanone	4 kilograms.
(xii) Methylamine and its salts	1 kilogram.
(xiii) Ethylamine and its salts	1 kilogram.
(xiv) Propionic anhydride	1 gram.
(xv) Isosafrole	4 kilograms.
(xvi) Safrole	4 kilograms.
(xvii) Piperonal	4 kilograms.
(xviii) N-Methylephedrine, its salts, optical isomers, and salts of optical isomers	1 kilogram.
(xix) N-Methylpseudoephedrine, its salts, optical isomers, and salts of optical isomers	1 kilogram.
(xx) Hydriotic acid (57%)	1.7 kilograms (or 1 liter by volume).
(xxi) Benzaldehyde	4 Kilograms.
(xxii) Nitroethane	2.5 Kilograms.

(2) List II Chemicals:

(i) Imports and Exports

Chemical	Threshold by volume	Threshold by weight
(A) Acetic anhydride	250 gallons	1,023 kilograms.
(B) Acetone	500 gallons	1,500 kilograms.
(C) Benzyl chloride	N/A	4 kilograms.
(D) Ethyl ether	500 gallons	1,364 kilograms.
(E) Potassium permanganate	N/A	500 kilograms.
(F) 2-Butanone (MEK)	500 gallons	1,455 kilograms.
(G) Toluene	500 gallons	1,591 kilograms.

(ii) Domestic Sales

Chemical	Threshold by volume	Threshold by weight
(A) Acetic anhydride	250 gallons	1,023 kilograms.
(B) Acetone	50 gallons	150 kilograms.
(C) Benzyl chloride	N/A	1 kilogram.
(D) Ethyl ether	50 gallons	135.8 kilograms.
(E) Potassium permanganate	N/A	55 kilograms.
(F) 2-Butanone (MEK)	50 gallons	145 kilograms.
(G) Toluene	50 gallons	159 kilograms.

(iii) The cumulative threshold is not applicable to domestic sales of Acetone, 2-Butanone (MEK), and Toluene.

(iv) Exports, transshipments and international transactions to Designated Countries set forth in § 1310.08(b)

(v) Export and International Transactions to Designated Countries, and Importations for Transshipment or Transfer to Designated Countries

Chemical	Threshold by volume	Threshold by weight
(A) Methyl Isobutyl Ketone (MIBK).	500 gallons	1523 kilograms.
(B) Reserved.		

(g) For listed chemicals for which no thresholds have been established, the size of the transaction is not a factor in determining whether the transaction meets the definition of a regulated transaction as set forth in § 1310.01(f). All such transactions, regardless of size, are subject to record-keeping and reporting requirements as set forth in this part 1310 and notification provisions as set forth in part 1313 of this chapter.

(1) Listed Chemicals For Which No Thresholds Have Been Established:

- (i) Ephedrine, its salts, optical isomers, and salts of optical isomers
- (ii) [Reserved]
- (2) [Reserved]

[54 FR 31665, Aug. 1, 1989, as amended at 56 FR 48733, Sept. 26, 1991; 57 FR 43615, Sept. 22, 1992; 59 FR 51367, Oct. 11, 1994; 60 FR 19510, Apr. 19, 1995; 60 FR 32460, June 22, 1995; 60 FR 42436, Aug. 16, 1995; 62 FR 5917, Feb. 10, 1997]

§ 1310.05 Reports.

(a) Each regulated person shall report to the Special Agent in Charge of the DEA Divisional Office for the area in which the regulated person making the report is located, as follows:

(1) Any regulated transaction involving an extraordinary quantity of a list-

ed chemical, an uncommon method of payment or delivery, or any other circumstance that the regulated person believes may indicate that the listed chemical will be used in violation of this part.

(2) Any proposed regulated transaction with a person whose description or other identifying characteristic the Administration has previously furnished to the regulated person.

(3) Any unusual or excessive loss or disappearance of a listed chemical under the control of the regulated person. The regulated person responsible for reporting a loss in-transit is the supplier.

(4) Any domestic regulated transaction in a tableting machine or an encapsulating machine.

(b) Each report submitted pursuant to paragraph (a) of this section shall, whenever possible, be made orally to the DEA Divisional Office for the area in which the regulated person making the report is located at the earliest practicable opportunity after the regulated person becomes aware of the circumstances involved and as much in advance of the conclusion of the transaction as possible. Written reports of transactions listed in paragraphs (a)(1), (a)(3) and (a)(4) of this section will subsequently be filed as set forth in § 1310.06 within 15 days after the regulated person becomes aware of the circumstances of the event. A transaction may not be completed with a person whose description or identifying characteristic has previously been furnished to the regulated person by the Administration unless the transaction is approved by the Administration.

(c) Each regulated person who imports or exports a tableting machine, or encapsulation machine, shall file a report (not a 486) of such importation or exportation with the Administration at the following address on or before the date of importation or exportation:

Drug Enforcement Administration, P.O. Box 28346, Washington, DC 20038. In order to facilitate the importation or exportation of any tableting machine or encapsulating machine and implement the purpose of the Act, regulated persons may wish to report to the Administration as far in advance as possible. A copy of the report may be transmitted directly to the Drug Enforcement Administration through electronic facsimile media. Any tableting machine or encapsulating machine may be imported or exported if that machine is needed for medical, commercial, scientific, or other legitimate uses. However, an importation or exportation of a tableting machine or encapsulating machine may not be completed with a person whose description or identifying characteristic has previously been furnished to the regulated person by the Administration unless the transaction is approved by the Administration.

(d) Each regulated bulk manufacturer of a listed chemical shall submit manufacturing, inventory and use data on an annual basis as set forth in § 1310.06(h). This data shall be submitted annually to the Drug and Chemical Evaluation Section, Drug Enforcement Administration (DEA), Washington, D.C. 20537, on or before the 15th day of March of the year immediately following the calendar year for which submitted. A business entity which manufactures a listed chemical may elect to report separately by individual location or report as an aggregate amount for the entire business entity provided that they inform the DEA of which method they will use. This reporting requirement does not apply to drug or other products which are exempted under §§ 1310.01(f)(1)(iv) or 1310.01(f)(1)(v) except as set forth in § 1310.06(h)(5). Bulk manufacturers that produce a listed chemical solely for internal consumption shall not be required to report for that listed chemical. For purposes of these reporting requirements, internal consumption shall consist of any quantity of a listed chemical otherwise not available for further resale or distribution. Internal consumption shall include (but not be limited to) quantities used for quality control testing, quantities consumed

in-house or production losses. Internal consumption does not include the quantities of a listed chemical consumed in the production of exempted products. If an existing standard industry report contains the information required in § 1310.06(h) and such information is separate or readily retrievable from the report, that report may be submitted in satisfaction of this requirement. Each report shall be submitted to the DEA under company letterhead and signed by an appropriate, responsible official. For purposes of this paragraph only, the term regulated bulk manufacturer of a listed chemical means a person who manufactures a listed chemical by means of chemical synthesis or by extraction from other substances. The term bulk manufacturer does not include persons whose sole activity consists of the repackaging or relabeling of listed chemical products or the manufacture of drug dosage form products which contain a listed chemical.

[54 FR 31665, Aug. 1, 1989, as amended at 57 FR 2461, Jan. 22, 1992; 61 FR 14024, Mar. 29, 1996; 61 FR 17958, Apr. 23, 1996; 62 FR 13968, Mar. 24, 1997]

§ 1310.06 Content of records and reports.

(a) Each record required by § 1310.03 shall include the following:

(1) The name, address, and, if required, DEA registration number of each party to the regulated transaction.

(2) The date of the regulated transaction.

(3) The name, quantity and form of packaging of the listed chemical or a description of the tableting machine or encapsulating machine (including make, model and serial number).

(4) The method of transfer (company truck, picked up by customer, etc.).

(5) The type of identification used by the purchaser and any unique number on that identification.

(b) For purposes of this section, normal business records shall be considered adequate if they contain the information listed in paragraph (a) of this section and are readily retrievable from other business records of the regulated person. For prescription drug products, prescription and hospital

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records kept in the normal course of medical treatment shall be considered adequate for satisfying the requirements of paragraph (a) of this section with respect to dispensing to patients, and records required to be maintained pursuant to the Federal Food and Drug Administration regulations relating to the distribution of prescription drugs, as set forth in 21 CFR part 205, shall be considered adequate for satisfying the requirements of paragraph (a) of this section with respect to distributions.

(c) Each report required by Section 1310.05(a) shall include the information as specified by Section 1310.06(a) and, where obtainable, the registration number of the other party, if such party is registered. A report submitted pursuant to § 1310.05(a)(1) or (a)(4) must also include a description of the circumstances leading the regulated person to make the report, such as the reason that the method of payment was uncommon or the loss unusual. If the report is for a loss or disappearance under § 1310.05(a)(4), the circumstances of such loss must be provided (in-transit, theft from premises, etc.)

(d) A suggested format for the reports is provided below:

Supplier:

Registration Number _____
 Name _____
 Business Address _____
 City _____
 State _____
 Zip _____
 Business Phone _____

Purchaser:

Registration Number _____
 Name _____
 Business Address _____
 City _____
 State _____
 Zip _____
 Business Phone _____
 Identification _____

Shipping Address (if different than purchaser Address):

Street _____
 City _____
 State _____
 Zip _____
 Date of Shipment _____
 Name of Listed Chemical(s) _____
 Quantity and Form of Packaging _____

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Description of Machine:

Make _____
 Model _____
 Serial # _____
 Method of Transfer _____

If Loss or Disappearance:

Date of Loss _____
 Type of Loss _____
 Description of Circumstances _____

Public reporting burden for this collection of information is estimated to average ten minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to the Drug Enforcement Administration, Records Management Section, Washington, D.C. 20537; and to the Office of Management and Budget, Paperwork Reduction Project No. 1117-0024, Washington, D.C. 20503.

(e) Each report of an importation of a tableting machine or an encapsulating machine required by § 1310.05(c) shall include the following information:

(1) The name, address, telephone number, tdlex number, and, where available, the facsimile number of the regulated person; the name, address, telephone number, telex number, and, where available, the facsimile number of the import broker or forwarding agent, if any:

(2) The description of each machine (including make, model, and serial number) and the number of machines being received;

(3) The proposed import date, and the first U.S. Customs Port of Entry; and

(4) The name, address, telephone number, telex number, and, where available, the facsimile number of the consignor in the foreign country of exportation.

(f) Each report of an exportation of a tableting machine or an encapsulating machine required by § 1310.05(c) shall include the following information:

(1) The name, address, telephone number, telex number, and, where available, the facsimile number of the regulated person; the name, address,

telephone number, telex number, and, where available, the facsimile number of the export broker, if any;

(2) The description of each machine (including make, model, and serial number) and the number of machines being shipped;

(3) The proposed export date, the U.S. Customs Port of exportation, and the foreign Port of Entry; and

(4) The name, address, telephone, telex, and, where available, the facsimile number of the consignee in the country where the shipment is destined; the name(s) and address(es) of any intermediate consignee(s).

(g) Declared exports of machines which are refused, rejected, or otherwise deemed undeliverable may be returned to the U.S. exporter of record. A brief written report outlining the circumstances must be sent to the Drug Enforcement Administration, P.O. Box 28346, Washington, DC 20038, following the return within a reasonable time. This provision does not apply to shipments that have cleared foreign customs, been delivered, and accepted by the foreign consignee. Returns to third parties in the United States will be regarded as imports.

(h) Each annual report required by Section 1310.05(d) shall provide the following information for each listed chemical manufactured:

(1) The name, address and chemical registration number (if any) of the manufacturer and person to contact for information.

(2) The aggregate quantity of each listed chemical that the company manufactured during the preceding calendar year.

(3) The year-end inventory of each listed chemical as of the close of business on the 31st day of December of each year. (For each listed chemical, if the prior period's ending inventory has not previously been reported to DEA, this report should also detail the beginning inventory for the period.) For purposes of this requirement, inventory shall reflect the quantity of listed chemicals, whether in bulk or non-exempt product form, held in storage for later distribution. Inventory does not include waste material for destruction, material stored as an in-process intermediate or other in-process material.

(4) The aggregate quantity of each listed chemical used for internal consumption during the preceding calendar year, unless the chemical is produced solely for internal consumption.

(5) The aggregate quantity of each listed chemical manufactured which becomes a component of a product exempted from Section 1310.01(f)(1)(iv) or 1310.01(f)(1)(v) during the preceding calendar year.

(6) Data shall identify the specific isomer, salt or ester when applicable but quantitative data shall be reported as anhydrous base or acid in kilogram units of measure.

[54 FR 31665, Aug. 1, 1989, as amended at 57 FR 2462, Jan. 22, 1992; 59 FR 51364, Oct. 11, 1994; 60 FR 32461, June 22, 1995; 61 FR 14024, Mar. 29, 1996; 61 FR 32926, June 26, 1996]

§ 1310.07 Proof of identity.

(a) Each regulated person who engages in a regulated transaction must identify the other party to the transaction. For domestic transaction, this shall be accomplished by having the other party present documents which would verify the identity, or registration status if a registrant, of the other party to the regulated person at the time the order is placed. For export transactions, this shall be accomplished by good faith inquiry through reasonably available research documents or publicly available information which would indicate the existence of the foreign customer. No proof of identity is required for foreign suppliers.

(b) The regulated person must verify the existence and apparent validity of a business entity ordering a listed chemical, tableting machine or encapsulating machine. For domestic transactions, this may be accomplished by such methods as checking the telephone directory, the local credit bureau, the local Chamber of Commerce or the local Better Business Bureau, or, if the business entity is a registrant, by verification of the registration. For export transactions, a good faith inquiry to verify the existence and apparent validity of a foreign business entity may be accomplished by such methods as verifying the business telephone listing through international telephone

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information, the firm's listing in international or foreign national chemical directories or other commerce directories or trade publications, confirmation through foreign subsidiaries of the U.S. regulated person, verification through the country of destination's embassy Commercial Attache, or official documents provided by the purchaser which confirm the existence and apparent validity of the business entity.

(c) When transacting business with a new representative of a firm, the regulated person must verify the claimed agency status of the representative.

(d) For sales to individuals or cash purchasers, the type of documents and other evidence of proof must consist of at least a signature of the purchaser, a driver's license and one other form of identification. Any exports to individuals or exports paid in cash are suspect and should be handled as such. For such exports, the regulated person shall diligently obtain from the purchaser or independently seek to confirm clear documentation which proves the person is properly identified such as through foreign identity documents, driver's license, passport information and photograph, etc. Any regulated person who fails to adequately prove the identity of the other party to the transaction may be subject to the specific penalties provided for violations of law related to regulated transactions in listed chemicals.

(e) For a new customer who is not an individual or cash customer, the regulated person shall establish the identity of the authorized purchasing agent or agents and have on file that person's signature, electronic password, or other identification. Once the authorized purchasing agent has been established, the agent list may be updated annually rather than on each order. The regulated person must ensure that shipments are not made unless the order is placed by an authorized agent of record.

(f) With respect to electronic orders, the identity of the purchaser shall consist of a computer password, identification number or some other means of

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identification consistent with electronic orders and with § 1310.07(e).

[54 FR 31665, Aug. 1, 1989, as amended at 60 FR 32461, June 22, 1995]

§ 1310.08 Excluded transactions.

Pursuant to 21 U.S.C. 802(39)(A)(iii), regulation of the following transactions has been determined to be unnecessary for the enforcement of the Chemical Diversion and Trafficking Act and, therefore, they have been excluded from the definitions of regulated transactions:

(a) Domestic and import transactions of hydrochloric and sulfuric acids.

(b) Exports, transshipments, and international transactions of hydrochloric and sulfuric acids, except for exports, transshipments and international transactions to the following countries:

- (1) Argentina
- (2) Bolivia
- (3) Brazil
- (4) Chile
- (5) Colombia
- (6) Ecuador
- (7) French Guiana
- (8) Guyana
- (9) Panama
- (10) Paraguay
- (11) Peru
- (12) Suriname
- (13) Uruguay
- (14) Venezuela

(c) Domestic transactions of Methyl Isobutyl Ketone (MIBK).

(d) Import transactions of Methyl Isobutyl Ketone (MIBK) destined for the United States.

(e) Export transactions, international transactions, and import transactions for transshipment or transfer of Methyl Isobutyl Ketone (MIBK) destined for Canada or any country outside of the Western Hemisphere.

[57 FR 43615, Sept. 22, 1992, as amended at 60 FR 19510, Apr. 19, 1995; 60 FR 32461, June 22, 1995; 62 FR 13968, Mar. 24, 1997]

§ 1310.09 Temporary exemption from registration.

(a) Each person required by section 302 of the act (21 U.S.C. 822) to obtain a registration to distribute, import, or export a combination epinephrine product is temporarily exempted from the

registration requirement, provided that the person submits a proper application for registration on or before July 12, 1997. The exemption will remain in effect for each person who has made such application until the Administration has approved or denied that application. This exemption applies only to registration; all other chemical control requirements set forth in parts 1309, 1310, and 1313 of this chapter remain in full force and effect.

(b) Each person required by section 302 of the act (21 U.S.C. 822) to obtain a registration to distribute, import, or export a drug product that contains pseudoephedrine or phenylpropanolamine that is regulated pursuant to § 1300.02(b)(28)(i)(D) of this chapter is temporarily exempted from the registration requirement, provided that the person submits a proper application for registration on or before December 3, 1997. The exemption will remain in effect for each person who has made such application until the Administration has approved or denied that application. This exemption applies only to registration; all other chemical control requirements set forth in parts 1309, 1310, and 1313 of this chapter remain in full force and effect.

[62 FR 27693, May 21, 1997, as amended at 62 FR 53960, Oct. 17, 1997]

§ 1310.10 Removal of the exemption of drugs distributed under the Food, Drug and Cosmetic Act.

(a) The Administrator may remove from exemption under § 1310.01(b)(28)(i)(D) any drug or group of drugs that the Administrator finds is being diverted to obtain a listed chemical for use in the illicit production of a controlled substance. In removing a drug or group of drugs from the exemption the Administrator shall consider:

- (1) The scope, duration, and significance of the diversion;
- (2) Whether the drug or group of drugs is formulated in such a way that it cannot be easily used in the illicit production of a controlled substance; and
- (3) Whether the listed chemical can be readily recovered from the drug or group of drugs.

(b) Upon determining that a drug or group of drugs should be removed from the exemption under paragraph (a) of this section, the Administrator shall issue and publish in the FEDERAL REGISTER his proposal to remove the drug or group of drugs from the exemption, which shall include a reference to the legal authority under which the proposal is based. The Administrator shall permit any interested person to file written comments on or objections to the proposal. After considering any comments or objections filed, the Administrator shall publish in the FEDERAL REGISTER his final order.

(c) The Administrator shall limit the removal of a drug or group of drugs from exemption under paragraph (a) of this section to the most identifiable type of the drug or group of drugs for which evidence of diversion exists unless there is evidence, based on the pattern of diversion and other relevant factors, that the diversion will not be limited to that particular drug or group of drugs.

(d) Any manufacturer seeking reinstatement of a particular drug product that has been removed from an exemption under paragraph (a) of this section, may apply to the Administrator for reinstatement of the exemption for that particular drug product on the grounds that the particular drug product is manufactured and distributed in a manner that prevents diversion. In determining whether the exemption should be reinstated the Administrator shall consider:

- (1) The package sizes and manner of packaging of the drug product;
- (2) The manner of distribution and advertising of the drug product;
- (3) Evidence of diversion of the drug product;
- (4) Any actions taken by the manufacturer to prevent diversion of the drug product; and
- (5) Such other factors as are relevant to and consistent with the public health and safety, including the factors described in paragraph (a) of this section as applied to the drug product.

(e) Within a reasonable period of time after receipt of the application for reinstatement of the exemption, the

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Administrator shall notify the applicant of his acceptance or non-acceptance of his application, and if not accepted, the reason therefor. If the application is accepted for filing, the Administrator shall issue and publish in the FEDERAL REGISTER his order on the reinstatement of the exemption for the particular drug product, which shall include a reference to the legal authority under which the order is based. This order shall specify the date on which it shall take effect. The Administrator shall permit any interested person to file written comments on or objections to the order. If any such comments raise significant issues regarding any finding of fact or conclusion of law upon which the order is based, the Administrator shall immediately suspend the effectiveness of the order until he may reconsider the application in light of the comments and objections filed. Thereafter, the Administrator shall reinstate, revoke, or amend his original order as he determines appropriate.

(f) Unless the Administrator has evidence that the drug product is being diverted, as determined by applying the factors set forth in paragraph (a) of this section, and the Administrator so notifies the applicant, transactions involving a specific drug product will not be considered regulated transactions during the following periods:

(1) While a bonafide application for reinstatement of exemption under paragraph (d) of this section for the specific drug product is pending resolution, provided that the application for reinstatement is filed not later than 60 days after the publication of the final order removing the exemption; and

(2) For a period of 60 days following the Administrator's denial of an application for reinstatement.

(g) An order published by the Administrator in the FEDERAL REGISTER, pursuant to paragraph (e) of this section, to reinstate an exemption may be modified or revoked with respect to a particular drug product upon a finding that:

(1) Applying the factors set forth in paragraph (a) of this section to the particular drug product, the drug product is being diverted; or

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(2) There is a significant change in the data that led to the issuance of the final rule.

[60 FR 32461, June 22, 1995, as amended at 62 FR 13968, Mar. 24, 1997]

§ 1310.11 Reinstatement of exemption for drug products distributed under the Food, Drug and Cosmetic Act.

(a) The Administrator has reinstated the exemption for the drug products listed in paragraph (e) of this section from application of sections 302, 303, 310, 1007, and 1008 of the Act (21 U.S.C. 822-823, 830, and 957-958), to the extent described in paragraphs (b), (c), and (d) of this section.

(b) No reinstated exemption granted pursuant to 1310.10 affects the criminal liability for illegal possession or distribution of listed chemicals contained in the exempt drug product.

(c) Changes in exempt drug product compositions: Any change in the quantitative or qualitative composition, trade name or other designation of an exempt drug product listed in paragraph (d) requires a new application for reinstatement of the exemption.

(d) The following drug products, in the form and quantity listed in the application submitted (indicated as the "date") are designated as reinstated exempt drug products for the purposes set forth in this section:

EXEMPT DRUG PRODUCTS

Supplier	Product name	Form	Date
[Reserved]	

[60 FR 32462, June 22, 1995]

§ 1310.14 Exemption of drug products containing ephedrine and therapeutically significant quantities of another active medicinal ingredient.

(a) Any manufacturer of a drug product containing ephedrine in combination with another active medicinal ingredient, the product formulation of which is not listed in the compendiums set forth in § 1310.01(b)(28)(i)(D)(I), may request that the Administrator exempt the product as one which contains ephedrine together with a therapeutically significant quantity of another active medicinal ingredient.

(b) An application for an exemption under this section shall contain the following information:

(1) The name and address of the applicant;

(2) The exact trade name of the drug product for which exemption is sought;

(3) The complete quantitative and qualitative composition of the drug product;

(4) A brief statement of the facts which the applicant believes justify the granting of an exemption under this section; and

(5) Certification by the applicant that the product may be lawfully marketed or distributed under the Food, Drug, and Cosmetic Act.

(6) The identification of any information on the application which is considered by the applicant to be a trade secret or confidential and entitled to protection under U.S. laws restricting the public disclosure of such information by government employees.

(c) The Administrator may require the applicant to submit such additional documents or written statements of fact relevant to the application which he deems necessary for determining if the application should be granted.

(d) Within a reasonable period of time after the receipt of a completed application for an exemption under this section, the Administrator shall notify the applicant of acceptance or non-acceptance of the application. If the application is not accepted, an explanation will be provided. The Administrator is not required to accept an application if any of the information required in paragraph (b) of this section or requested pursuant to paragraph (c) of this section is lacking or not readily understood. The applicant may, however, amend the application to meet the requirements of paragraphs (b) and (c) of this section. If the application is accepted for filing, the Administrator shall issue and publish in the FEDERAL REGISTER an order on the application, which shall include a reference to the legal authority under which the order is based. This order shall specify the date on which it shall take effect. The Administrator shall permit any interested person to file written comments on or objections to the order. If any comments or objections raise signifi-

cant issues regarding any findings of fact or law upon which the order is based, the Administrator shall immediately suspend the effectiveness of the order until he may reconsider the application in light of the comments and objections filed. Thereafter, the Administrator shall reinstate, revoke, or amend the original order as deemed appropriate.

[60 FR 32462, June 22, 1995, as amended at 62 FR 13968, Mar. 24, 1997]

§ 1310.15 Exempt drug products containing ephedrine and therapeutically significant quantities of another active medicinal ingredient.

(a) The drug products containing ephedrine and therapeutically significant quantities of another active medicinal ingredient listed in paragraph (e) of this section have been exempted by the Administrator from application of sections 302, 303, 310, 1007, and 1008 of the Act (21 U.S.C. 822-3, 830, and 957-8) to the extent described in paragraphs (b), (c), and (d) of this section.

(b) No exemption granted pursuant to § 1310.14 affects the criminal liability for illegal possession or distribution of listed chemicals contained in the exempt drug product.

(c) Changes in drug product compositions: Any change in the quantitative or qualitative composition of an exempt drug product listed in paragraph (d) requires a new application for exemption.

(d) In addition to the drug products listed in the compendium set forth in § 1310.01(b)(28)(i)(D)(I), the following drug products, in the form and quantity listed in the application submitted (indicated as the "date") are designated as exempt drug products for the purposes set forth in this section:

EXEMPT DRUG PRODUCTS CONTAINING EPHEDRINE AND THERAPEUTICALLY SIGNIFICANT QUANTITIES OF ANOTHER ACTIVE MEDICINAL INGREDIENT

Supplier	Product name	Form	Date
[Reserved]	

[60 FR 32463, June 22, 1995, as amended at 62 FR 13968, Mar. 24, 1997]

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